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10/521,289	01/14/2005	Hubrecht Lambertus Tjalling De Blick	NL 020623	8513
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BRIARCLIFF MANOR, NY 10510		ART UNIT	PAPER NUMBER	
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SHORTENED STATUTOR	RY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE	
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Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

	Application No.	Applicant(s)				
Office Action Summary	10/521,289	DE BLIEK, HUBRECHT LAMBERTUS TJALLING				
omee Action Summary	Examiner	Art Unit				
	Said Broome	2628				
The MAILING DATE of this communication Period for Reply	n appears on the cover sheet wi	ith the correspondence address				
A SHORTENED STATUTORY PERIOD FOR RIWHICHEVER IS LONGER, FROM THE MAILIN - Extensions of time may be available under the provisions of 37 Cl after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory provided to reply within the set or extended period for reply will, by any reply received by the Office later than three months after the earned patent term adjustment. See 37 CFR 1.704(b).	G DATE OF THIS COMMUNION (FR 1.136(a). In no event, however, may a right. Beriod will apply and will expire SIX (6) MON statute, cause the application to become AB	CATION. reply be timely filed ITHS from the mailing date of this communication. BANDONED (35 U.S.C. § 133).				
Status						
1) Responsive to communication(s) filed on	<u>03 November 2006</u> .					
2a)⊠ This action is FINAL . 2b)□	This action is FINAL . 2b) ☐ This action is non-final.					
	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
closed in accordance with the practice und	der <i>Ex parte Quayle</i> , 1935 C.D). 11, 453 O.G. 213.				
Disposition of Claims						
4)⊠ Claim(s) <u>1-4 and 6-9</u> is/are pending in the 4a) Of the above claim(s) is/are witl						
5) Claim(s) is/are allowed.		•				
6)⊠ Claim(s) <u>1-4 and 6-9</u> is/are rejected.						
7) Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction a	nd/or election requirement.					
Application Papers						
9) The specification is objected to by the Exa	miner.					
10) The drawing(s) filed on is/are: a)		by the Examiner.				
Applicant may not request that any objection to	the drawing(s) be held in abeyar	nce. See 37 CFR 1.85(a).				
Replacement drawing sheet(s) including the control of the oath or declaration is objected to by the						
Priority under 35 U.S.C. § 119	. ·					
12)⊠ Acknowledgment is made of a claim for for a)⊠ All b)□ Some * c)□ None of:	reign priority under 35 U.S.C. §	§ 119(a)-(d) or (f).				
 Certified copies of the priority docu 	ments have been received.					
2. Certified copies of the priority docu						
3. Copies of the certified copies of the		received in this National Stage				
application from the International B	•	resolved				
* See the attached detailed Office action for	a list of the certified copies flot	received.				
Attachment(s)						
1) Notice of References Cited (PTO-892)	· 	Summary (PTO-413)				
 2) Notice of Draftsperson's Patent Drawing Review (PTO-94 3) Information Disclosure Statement(s) (PTO/SB/08) 	· ·	s)/Mail Date Informal Patent Application				
Paper No(s)/Mail Date	6) Other:	<u>_</u> .				

DETAILED ACTION

Response to Amendment

- 1. This office action is in response to an amendment filed on 11/3/2006.
- 2. Claims 1, 3, 4, 8 and 9 have been amended by the applicant.
- 3. Claim 5 has been cancelled by the applicant.
- 4. Claims 2, 6 and 7 are original.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 8 is rejected under 35 U.S.C. 101 because it contains the statement: "A tangible media containing code for a computer program characterized...", which is non-statutory subject matter because a program must be encoded on a computer readable medium for causing the computer to execute in order to be considered statutory subject matter. Similarly, computer programs claimed as computer listings per se, i.e., the descriptions or expressions of the programs, are not physical "things." They are neither computer components nor statutory processes, as they are not "acts" being performed. Such claimed computer programs do not define any structural and functional interrelationships between the computer program and other claimed elements of a computer which permit the computer program's functionality to be realized. In contrast, a claimed computer-readable medium encoded with a computer program is a computer element which defines structural and functional interrelationships between the computer program and the rest of the computer which permit the computer program's

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functionality to be realized, and is thus statutory. See Lowry, 32 F.3d at 1583-84, 32 USPQ2d at 1035. Accordingly, it is important to distinguish claims that define descriptive material per se from claims that define statutory inventions.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3 and 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schneider (US Patent 5,531,227) in view of Burke et al.(hereinafter "Burke", US Patent 6,421,454).

Regarding claim 1, 8 and 9, Schneider teaches a method of producing and displaying an image on a display screen of a volume from a multi-dimensional object data set in column 8 lines 4-7 ("...to gather follow image information, an MRI scan of the patient's head and stereotactic frame is taken, and the three-dimensional data (including coordinate data relating to the patient's head and the stereotactic frame) are processed..."), and is also shown in Figure 1 as element 20. Schneider also teaches a computer system in column 7 lines 14-20 ("Processing means 16 may be a stand-alone computer such as a SGI RealityEngine (available from Silicon Graphics, Inc.) which has been loaded with suitable software. Alternatively, processing means 16 may be an image processor specially designed for this particular application.") that performs the processing of the image graphics data, therefore the computer program or software contained

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on a tangible media, as described in column 7 lines 3-9, as recited in claim 8 is run on the computer system 16, as illustrated in Figure 2 and as recited in claim 9. Schneider teaches a surface associated with the volume is identified in column 5 lines 13-26 ("Typically the lead" view is the line of view through which the physician at any given time wishes to view the procedure...the lead view is the physician's view of the surface of the patient, the lead image could be a corresponding video image of the surface of the patient.") and in column 9 lines 62-67 ("...real time lead images of the patient's head along the physician's line of sight are obtained..."), where it is described that the user identifies a certain region of the surface. Schneider also teaches an initial position on the identified surface is selected in column 9 lines 43-45 ("...the fiducial marker can be added to the object prior to imaging solely for the purpose of providing a unique marker, such as a marker on the scalp. Such a marker would typically be selected to be visible..."). Schneider also teaches at least one depth associated with the identified surface is selected and a reformat slice is produced from the object data set at the selected depth along the normal to the identified surface at the selected initial position in column 11 lines 29-34 ("The three-dimensional follow image is also sliced to a depth selected via a depth control."), where it is described that the follow image slice, which resides in the image plane orthogonal to the user, as described in column 5 lines 29-35 ("A properly sliced and transformed follow image will usually be in a plane parallel with that of the lead image, and consequently, orthogonal to the lead view..."), is therefore produced at a certain depth along the normal. Schneider teaches a resulting image is displayed on a display screen in column 10 lines 47-51 and as shown in Figure 1 as element 20. However, Schneider fails to teach a depth associated with the surface selected from a priori information. Burke teaches a depth associated

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with the surface selected from a priori information in column 11 lines 22-25 ("...an embodiment of the invention which locates the depth of solid features of interest. Such features are preferably user selected...") and in column 11 lines 51-53 ("The plane with the maximum correlation for the feature of interest and its associated depth Z_n are stored in memory..."), where the depth is determined based on predetermined information regarding the structure of interest selected by a user. It would have been obvious to one of ordinary skill in the art to combine the teachings of Schneider with Burke because this combination would provide a user with a slice of a region of interest within a volume where the selection of the slice is determined using information regarding a specific structure within the volume without requiring a specific depth.

Regarding claim 2, Schneider teaches at least one further position on the identified surface is selected in column 9 lines 59-62 ("...the fiducial markers in the lead images have been identified, the system is ready for use in real time imaging during a medical procedure."), where it is described that multiple markers are used to identify surfaces. Schneider also teaches a reformat slice is produced at said selected depth along the normal to the identified surface at said further selected position in column 11 lines 29-34 ("The three-dimensional follow image is also sliced to a depth selected via a depth control."), where it is described that the follow image slice, which resides in the image plane orthogonal to the user, as described in column 5 lines 29-35 ("A properly sliced and transformed follow image will usually be in a plane parallel with that of the lead image, and consequently, orthogonal to the lead view..."), is therefore produced at a certain depth along the normal.

Regarding claim 3, Schneider teaches a method of producing and displaying an image on a display screen of a volume from a multi-dimensional object data set in column 8 lines 4-7

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("...to gather follow image information, an MRI scan of the patient's head and stereotactic frame is taken, and the three-dimensional data (including coordinate data relating to the patient's head and the stereotactic frame) are processed..."), and is also shown in Figure 1 as element 20. Schneider teaches a surface associated with the volume is identified in column 5 lines 13-26 ("Typically the lead view is the line of view through which the physician at any given time wishes to view the procedure...the lead view is the physician's view of the surface of the patient, the lead image could be a corresponding video image of the surface of the patient.") and in column 9 lines 62-67 ("...real time lead images of the patient's head along the physician's line of sight are obtained..."), where it is described that the user identifies a certain region of the surface. Schneider also teaches an initial position on the identified surface is selected in column 9 lines 43-45 ("...the fiducial marker can be added to the object prior to imaging solely for the purpose of providing a unique marker, such as a marker on the scalp. Such a marker would typically be selected to be visible..."). Schneider also teaches at least one depth associated with the identified surface is selected and a reformat slice is produced from the object data set at the selected depth along the normal to the identified surface at the selected initial position in column 11 lines 29-34 ("The three-dimensional follow image is also sliced to a depth selected via a depth control."), where it is described that the follow image slice, which resides in the image plane orthogonal to the user, as described in column 5 lines 29-35 ("A properly sliced and transformed follow image will usually be in a plane parallel with that of the lead image, and consequently, orthogonal to the lead view..."), is therefore produced at a certain depth along the normal. Schneider teaches a resulting image is displayed on a display screen in column 10 lines 47-51 and as shown in Figure 1 as element 20. Schneider teaches reformat slices are produced

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perpendicular to the normal to the identified surface at the selected position in column 5 lines 29-35 ("A properly sliced and transformed follow image will usually be in a plane parallel with that of the lead image, and consequently, orthogonal to the lead view..."), where it is described that slices are orthogonal, or perpendicular, to the normal or line of view to the identified surface at the selected position. Schneider fails to teach the depth associated with the identified surface is selected by selecting one of those reformat slices. Burke teaches the depth associated with the identified surface is selected by selecting one of those reformat slices in column 11 lines 34-40 ("The image processor 14 then selects (step 134) a planar slice at depth Z_n from the three dimensional ultrasound data..."), where it is described that the slice is selected at a certain depth. It would have been obvious to one of ordinary skill in the art to combine the teachings of Schneider with Burke because this combination would provide a slice of region of interest within a volume, as taught by Schneider in column 10 lines 44-47, where the depth would be determined based on the selection of the slice of interest without requiring prior depth data, as taught by Burke in column 11 lines 22-25-34-35, and as disclosed in the applicant's Specification on page 6 lines 3-5.

Regarding claim 6, Schneider teaches the reformat slice is perpendicular to the normal to the identified surface at the selected point on the identified surface, at the point on the reformat slice where the reformat slice is intersected by said normal to the identified surface in column 5 lines 29-35 ("A properly sliced and transformed follow image will usually be in a plane parallel with that of the lead image, and consequently, orthogonal to the lead view..."), where it is described that slices are orthogonal, or perpendicular, to the normal or line of view that corresponds to the identified surface at the selected position, as described in column 5 lines 12-

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15 ("..."lead view" means the line of view toward the object at any given time. Typically the lead view is the line of view through which the physician at any given time wishes to view the procedure.").

Regarding claim 7, Schneider teaches a reformat slice, which is slice produced from the three-dimensional image at a certain depth as described in column 11 lines 29-34 ("The three-dimensional follow image is also sliced to a depth selected via a depth control."), and is produced from a stack of reformat slices produced perpendicular to the normal to the selected point on the surface, as described in column 2 lines 24-28 ("A computer develops a three-dimensional image of the patient's skull (including the markers) by taking a series of "slices" or planar images at progressive locations, as is common for CT imaging, then interpolating between the slices to build the three-dimensional image."), where it is described that it is known in the art that three-dimensional volumetric images are a collection of several slices at different depth values, therefore the three-dimensional image, as described in column 10 lines 28-39 ("...slicing algorithms involve designating a plane of slice in the three-dimensional image and instructing the computer to ignore or to make transparent any data located between the viewer and that plane...The resulting image is a two-dimensional representation of the view into the three-dimensional object sliced at the designated plane."), is a stack of slices.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schneider (US Patent 5,531,227) in view of Yanof et al.(hereinafter "Yanof", US Patent 5,371,778).

Regarding claim 4, Schneider teaches a method of producing and displaying an image on a display screen of a volume from a multi-dimensional object data set in column 8 lines 4-7

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("...to gather follow image information, an MRI scan of the patient's head and stereotactic frame is taken, and the three-dimensional data (including coordinate data relating to the patient's head and the stereotactic frame) are processed..."), and is also shown in Figure 1 as element 20. Schneider teaches a surface associated with the volume is identified in column 5 lines 13-26 ("Typically the lead view is the line of view through which the physician at any given time wishes to view the procedure...the lead view is the physician's view of the surface of the patient, the lead image could be a corresponding video image of the surface of the patient.") and in column 9 lines 62-67 ("...real time lead images of the patient's head along the physician's line of sight are obtained..."), where it is described that the user identifies a certain region of the surface. Schneider also teaches an initial position on the identified surface is selected in column 9 lines 43-45 ("...the fiducial marker can be added to the object prior to imaging solely for the purpose of providing a unique marker, such as a marker on the scalp. Such a marker would typically be selected to be visible..."). Schneider also teaches at least one depth associated with the identified surface is selected and a reformat slice is produced from the object data set at the selected depth along the normal to the identified surface at the selected initial position in column 11 lines 29-34 ("The three-dimensional follow image is also sliced to a depth selected via a depth control."), where it is described that the follow image slice, which resides in the image plane orthogonal to the user, as described in column 5 lines 29-35 ("A properly sliced and transformed follow image will usually be in a plane parallel with that of the lead image, and consequently, orthogonal to the lead view..."), is therefore produced at a certain depth along the normal. Schneider teaches a resulting image is displayed on a display screen in column 10 lines 47-51 and as shown in Figure 1 as element 20. Schneider also describes a depth associated with

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the identified surface that is selected from a view of a plane in column 4 lines 62-64 ("...the displayed (x,y) plane is selected by adjusting the selected distance along the z-axis"). However, Schneider fails to teach a depth associated with a created transverse view. Yanof describes a transverse view, which includes the identified surface and the selected point in column 4 lines 53-58 ("...A second view port 32 displays the data along the transverse plane 10 through the position of the cursor...the displayed (x,y) plane is selected by adjusting the selected distance along the z-axis."), where it is described that a transverse view is established which includes the identified surface and selected point at a certain depth, as described in column 5 lines 26-40 ("...the operator may define cutting planes, either parallel to one of the transverse, coronal, or sagittal planes, or oblique cutting planes...the projection image can be edited for tissue type to "peel away" selected tissue types, thereby providing a new surface for the cursor to traverse...the operator can also edit voxels based on other criteria. For example, air, soft tissue, bone, and other types of imaged subject matter have CT numbers in distinct ranges...the operator may choose to edit all voxels except those with CT numbers corresponding to bone "). It would have been obvious to one of ordinary skill in the art to combine the teachings of Schneider with Yanof because this combination would provide a user with a slice of a specific area of interest within a volume, as taught by Schneider in column 10 lines 44-47, where selection of that slice is designated using data associated with the region of interest, as taught by Yanof in column 5 lines 32-40, thereby enabling analysis of a particular region of interest without requiring a specific depth.

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Response to Arguments

Applicant's arguments filed 11/3/2006 with respect to claims 1-4 and 6-9 have been considered but are most in view of the new ground(s) of rejection.

The applicant argues that the references Schneider in view of Burke with regards to claim 1 do not teach a depth associated with the identified surface is selected from priori information. The examiner maintains the rejection because Burke teaches a predetermined depth in column 11 lines 22-25, where the depth of the area of interest is acquired based on information specific to the region of interest, as disclosed in the applicant's Specification on page 4 lines 17-20.

The applicant also argues that the motivations to combine the references in rejection of claims 3 and 4 are based on hindsight. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Regarding claim 3, it would have been obvious to one of ordinary skill in the art to combine the teachings of Schneider with Burke because this combination would provide a slice of a region of interest within a volume, as taught by Schneider in column 10 lines 44-47, where the depth would be determined based on the selection of the slice of interest without requiring prior depth data, as taught by Burke in column 11 lines 22-25-34-35, and as disclosed in the applicant's Specification on page 6 lines 3-5.

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Regarding claim 4, it would have been obvious to one of ordinary skill in the art to combine the teachings of Schneider with Yanof because this combination would provide a user with a specific area of interest within a slice of volumetric data, as taught by Schneider in column 10 lines 44-47, where selection of that slice is designated using data associated with the region of interest, as taught by Yanof in column 5 lines 26-40, thereby enabling analysis of the particular region of interest without requiring a specific depth.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Said Broome whose telephone number is (571)272-2931. The examiner can normally be reached on 8:30am-5pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ulka Chauhan can be reached on (571)272-7782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

S. Broome 1/5/07

ULKA CHAUHAN SUPERVISORY PATENT EXAM**INE**R